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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,694	10/29/2003	Rolf Forster	13648	5073
7590 09/15/2005			EXAMINER	
ORUM & ROTH 53 W. JACKSON BLVD CHICAGO, IL 60604			WERNER, JONATHAN S	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,694

Applicant(s)

FORSTER, ROLF

Examiner

Jonathan Werner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/29/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/19/03 was filed before the mailing date of the first Office Action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. **Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.** If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)),

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and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).

"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, for reciting the limitation "antibacterial" in said additive. There is insufficient antecedent basis for this limitation in the claim.

Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, for lacking clarity in relation to the claims they depend on in accordance with the subject matter which applicant regards as the invention since the "volatile" components claimed have already been "driven out from the orthodontic appliance" and therefore show no further utility related to the scope of invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-14, 16-17, and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Masel (5,674,067). In re claim 1, Masel discloses an orthodontic appliance which is made of a plastic material having a water absorption capacity (thermoplastic polyurethane elastomer - col 6 ln 34) and which is impregnated with a water-soluble additive (col 5 ln 66). In re claims 2-11, it should be noted that applicant is claiming an article of manufacture and not the process of forming/making the device. The process and the intermediate products used in the process by which the device is made are not given patentable weight because a product claim is properly met if the final product is shown regardless of the process used. Accordingly, the manner in which the device is formed, i.e. injection molding the plastic material, is given little weight. In re claim 12, Masel discloses the selected additive is one that has an anti-bacterial effect (col 7 ln 26). In re claims 13 and 14, Masel discloses an orthodontic appliance that contains pores and micropores (col 8 ln 14). In re claims 16 and 17, Masel discloses the additive has a wetting property (col 7 ln 3) and includes a wetting agent (col 7 ln 25). In re claims 24-29, it should be noted that applicant is claiming an article of manufacture and not the process of forming/making the device. The process and the intermediate products used in the process by which the device is made are not

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given patentable weight because a product claim is properly met if the final product is shown regardless of the process used. Accordingly, the manner in which the device is formed, i.e. injection molding the plastic material, is given little weight. Furthermore, the composition of the volatile components that are driven out of the appliance during the process is given little patentable weight for the same reason.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masel in view of Quast (5,736,158). Masel discloses an orthodontic appliance as previously described but lacks an aminofluoride or tin fluoride wetting agent. However, Quast teaches the use of an aminofluoride or a tin fluoride in an orthodontic appliance (col 3 ln 40). Therefore, it would be obvious to one having ordinary skill in the art at the time of applicant's invention to include aminofluoride or tin fluoride as a wetting agent in order to clean and protect the teeth and gums when released in the mouth as taught by Quast.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masel in view of Gieske (4,051,234). Masel discloses an orthodontic appliance as previously

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described but lacks octadecenylamine – hydrofluoride as a wetting agent. However, Gieske teaches the use of octadecenylamine – hydrofluoride (col 11 ln 33). Therefore, it would be obvious to one having ordinary skill in the art at the time of applicant's invention to include octadecenylamine – hydrofluoride as a wetting agent in order to inhibit the formation of plaque and stains on oral surfaces as taught by Gieske.

10. Claims 22 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masel in view of Schmitt (6,138,315). Masel discloses an orthodontic appliance as previously described but lacks an additive that is or includes a derivative of hexamethylene bisguanide. Schmitt, however, teaches the use of chlorohexidine digluconate (col 4 ln 10) as an anti-microbial active compound. Therefore, it would be obvious to one having ordinary skill in the art at the time of applicant's invention to include chlorohexidine digluconate as an anti-microbial active compound in order to inhibit the growth of bacteria and other micro-organisms thereby avoiding the possibility of infecting oral gums as taught by Schmitt.

11. Claims 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masel in view of Forster (5,820,371). In re claim 15, Masel discloses an orthodontic appliance as previously described. However, Masel fails to disclose the use of polyarylether ketone. Forster, however, teaches the use of polyarylether ketone. Therefore, it would be obvious to one having ordinary skill in the art at the time of applicant's invention to make the plastic bracket out of polyarylether ketone in order to

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increase strength, toughness, and chemical resistance of the appliance as taught by Forster.

In re claim 23, Masel discloses an orthodontic appliance as previously described but fails to show a bracket or a buccal tube. Forster, however, teaches the use of a plastic bracket or buccal tube. Therefore, it would be obvious to one having ordinary skill in the art at the time of applicant's invention to make the orthodontic appliance a bracket or buccal tube in order to use the device in teeth-straightening procedures where the appliance is in close contact with the surfaces of the teeth.

Conclusion

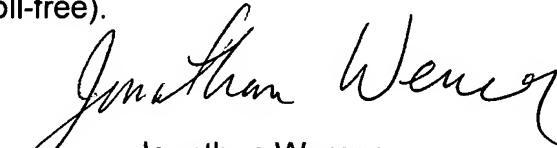
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mottate (6,358,043), Sachdeva (5,232,361), Masumoto (5,954,501), Orikasa (5,595,484), Reher (5,074,783), Barry (6,267,590), Forman (5,716,208), and Wallshein (3,205,576) all disclose prior art related to an orthodontic appliance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

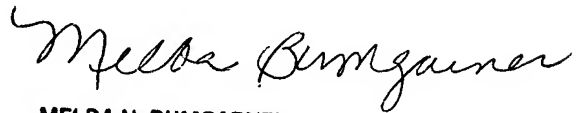
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jonathan Werner
Examiner
AU 3732

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9/8/05



MELBA N. BUMGARNER
PRIMARY EXAMINER